NOTE

Flexible yet Tailored: Developing a Standard for Patent Nonobviousness in Biological and Chemical Technologies Consistent with *KSR*

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INTRODUCTION

Even in the early years of U.S. independence, the founding fathers recognized a need to "promote the Progress of Science and useful Arts."[1] To achieve this, they wrote into the Constitution a mechanism via which inventors could "secur[e] for limited Times . . . the exclusive Right to their respective . . . Discoveries."[2] At the outset, the text of the Constitution ostensibly sets a precondition for these discoveries to be "useful" in order for Congress to be justified in encouraging such acts of discovery and invention.[3] Translated to the Patent Act[4] and codified,[5] this requirement of usefulness has been suggested to indicate that an invention should possess both practical and commercial usefulness in order to justify patent eligibility.[6] In addition to usefulness, an invention has to satisfy the statutory requirements of adequate disclosure,[7] novelty,[8] and nonobviousness.[9] The focus of this Note is on the current judicial state of the nonobviousness requirement, subsequent to the landmark Supreme Court case *KSR Int'l Co. v. Teleflex Inc.*[10] ("*KSR*"). More specifically, this Note focuses on the Federal Circuit's nonobviousness jurisprudence regarding biological and chemical ("biochem") technologies.

Nonobviousness has been called "the ultimate condition of patentability."[11] As set forth in 35 U.S.C. section 103, an invention is not patentable if the differences between the invention and the prior art would have made the invention as a whole obvious to a person

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[1] U.S. CONST. art. I, § 8, cl. 8.

[2] *Id.* The language was incorporated into the Constitution in 1787. 1 WILLIAM F. PATRY, COPYRIGHT LAW AND PRACTICE 24 (1994).

[3] *See* U.S. CONST. art. I, § 8, cl. 8.

[4] U.S. Patent Act of 1952, Pub. L. No. 593, § 101, 66 Stat. 792, 797 (codified as amended at 35 U.S.C. § 101 (2018)).

[5] 35 U.S.C. § 101 (2018).

[6] *See* Michael Risch, *Reinventing Usefulness*, 2010 BYU L. REV. 1195, 1197-98, 1203-06.

[7] 35 U.S.C. § 112 (2018).

[8] 35 U.S.C. § 102 (2018).

[9] 35 U.S.C. § 103 (2018).

[10] 550 U.S. 398 (2007). In this case, the Supreme Court reversed the Federal Circuit's decision — the Court ruled that a patent claim disclosing a position-adjustable pedal assembly with an attached electronic sensor was invalid as obvious; this is discussed in more detail in Part I.B.

[11] Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 13 (1992) (quoting NONOBVIOUSNESS – THE ULTIMATE CONDITION OF PATENTABILITY (John F. Witherspoon ed., 1980)).

having ordinary skill in the art ("PHOSITA").[12] Prior art is generally defined as all publicly available information pertaining and pertinent to the invention sought to be patented.[13] The text of 35 U.S.C. section 103 makes prior art one critical consideration in nonobviousness.[14] Additionally, when an invention is compared with prior art, it must amount to more than just a trivial advance over prior art to be considered nonobvious.[15] In other words, the invention must be more than just slightly different or modified from prior art to qualify as being patentable.[16]

The nonobviousness requirement serves primarily as a gatekeeper against inventions that have not made significantly large advancements or improvements over prior art.[17] This is because granting patents to these inventions would impose unjustifiable costs on the public.[18] Such costs arise in two related situations. First, allowing inventions that represent only a minimal improvement over existing technology to be patented would flood the patent landscape with patents that are very similar.[19] If this were to occur, patent due diligence would slow to a snail's pace, and patentees would find it vexatious to protect themselves against infringement litigation.[20] This would reduce public welfare by imposing high search and transaction costs and reducing access to resources.[21] Second, urgent market demand sometimes spurs the invention of a certain product that would have been invented absent any patent incentive.[22] In this situation, multiple competitors might work on inventing the product contemporaneously. Awarding one party the patent to the exclusion of the others would be detrimental to the patentee's competitors and discourage further innovation.[23] Consequently, and more importantly,

[12] 35 U.S.C. § 103.

[13] *See* 3 ROBERT A. MATTHEWS, JR., ANNOTATED PATENT DIGEST § 15:59 (2018).

[14] *See* 35 U.S.C. § 103.

[15] Merges, *supra* note 11, at 13-14.

[16] *See id.* at 13.

[17] Christopher A. Cotropia, *Nonobviousness and the Federal Circuit: An Empirical Analysis of Recent Case Law*, 82 NOTRE DAME L. REV. 911, 916 (2007); Lee Petherbridge, *On the Development of Patent Law*, 43 LOY. L.A. L. REV. 893, 906-08 (2010).

[18] *See* Petherbridge, *supra* note 17, at 906.

[19] *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY 609-10 (6th ed. 2013).

[20] *See id.* at 610.

[21] *See id.*; Merges, *supra* note 11, at 13-14.

[22] MERGES & DUFFY, *supra* note 19, at 608-09.

[23] *See id.*

this would deny consumers the benefit of choosing from several products whose prices would have been driven down by competition.[24]

The nebulous nature of what it means to be obvious also complicates a statutory finding of obviousness. Stated simply, something obvious to one person might be completely nonobvious to another.[25] Against this subjective backdrop, federal courts are tasked with determining which side prevails and whether a patentee is allowed to keep their patent.[26] Historically, the analysis for obviousness begins with an examination of the prior art, because it is only with reference to a previous invention that a current invention can be said to fail the nonobviousness requirement.[27] After this point in the analysis, the substantive challenge for courts has been building a framework upon which to perform an accurate analysis.[28] Such a framework should be facile to apply consistently, comport with statutory intent, and adapt to different kinds of inventions.[29]

This Note considers the ways that the Federal Circuit has dealt with the question of obviousness following the Supreme Court's decision in *KSR*. To begin, Part I of this Note examines the Federal Circuit's pre-*KSR* standards, the Supreme Court's rejection of the Federal Circuit's rigid application of these standards, and the broad principles set forth in *KSR*. Next, Part II criticizes the Federal Circuit's inconsistencies in applying *KSR* standards, analyzing how its decisions could result in legal and public inefficiencies. Finally, this Note concludes by suggesting that the Federal Circuit adopt a more efficient standard in examining biochem technologies, based on the standard of the

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[24] *See id.*

[25] *See, e.g.*, Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1409 (2006) [hereinafter *Patently Non-Obvious*] (showing that amongst a group of pre-first year law students presented with fact scenarios for two inventions, there was no statistical consensus whether each invention was obvious or nonobvious). Presumably, this effect would be mitigated by applying the standard of a person having ordinary skill in the art, because this is an objective standard. *See* Greg Reilly, *Rethinking the PHOSITA in Patent Litigation*, 48 LOY. U. CHI. L.J. 501, 507-08 (2016).

[26] *See* Douglas L. Rogers, *Federal Circuit's Obviousness Test for New Pharmaceutical Compounds: Gobbledygook?*, 14 CHI.-KENT J. INTELL. PROP. 49, 55 (2014).

[27] *See* Hotchkiss v. Greenwood, 52 U.S. 248, 266-67 (1850) (introducing the idea of non-obviousness into patent law after invalidating a patent which had "an absence of that degree of skill and ingenuity which constitute essential elements of every invention").

[28] *See* Petherbridge, *supra* note 17, at 906-08.

[29] *See id.*

PHOSITA. This standard should be distinct from that of other types of technologies, but still conform to the flexible principles of *KSR*.

I. THE SUPREME COURT'S REJECTION OF THE FEDERAL CIRCUIT'S FORMALISTIC TEST FOR NONOBVIOUSNESS

A. The "Teaching, Suggestion, or Motivation" ("TSM") Test of the Federal Circuit

In 1982, Congress enacted the Federal Courts Improvement Act ("FCIA").[30] This Act merged the United States Court of Customs and Patent Appeals and the appellate division of the United States Court of Claims to create the Court of Appeals for the Federal Circuit.[31] Congress enacted FCIA in order to address the vastly inconsistent ways that federal courts were interpreting patent law across the country.[32] The power of appellate jurisdiction over patent actions was thus consolidated in the Federal Circuit.[33] In the twenty-five years leading up to *KSR*, the Federal Circuit developed the TSM test and routinely applied it to patent appeal cases when evaluating whether a disputed patent was obvious and therefore invalidly patented.[34]

Under the TSM test, courts examine a patent claim with reference to the prior art, nature of the problem, and knowledge of a PHOSITA.[35] The patent claim is obvious if any of these factors provided some motivation or suggestion for the inventor to combine the prior art to create the invention.[36] In developing the TSM test, the Federal Circuit focused on having an objective analytical framework, informed by "objective inputs and transparent decision making."[37] From the foregoing formulation, one can reasonably conclude that the two

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[30] Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.).

[31] *See id.*

[32] S. REP. NO. 97-275, at 4-5 (1981), *as reprinted in* 1982 U.S.C.C.A.N. 11, 14-15 ("[P]atent law [is] an area in which the application of the law to the facts of a case often produces different outcomes in different courtrooms in substantially similar cases . . . . The creation of . . . the Federal Circuit will produce desirable uniformity in this area of the law.").

[33] Federal Courts Improvement Act § 127, 96 Stat. at 37-38.

[34] *See* Petherbridge, *supra* note 17, at 910-12.

[35] *E.g.*, Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1321-22 (Fed. Cir. 2005); Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1323-24 (Fed. Cir. 1999).

[36] *Al-Site Corp.*, 174 F.3d at 1323-24.

[37] Petherbridge, *supra* note 17, at 914.

decisive determinants of nonobviousness are the PHOSITA and the prior art.

A PHOSITA — the first determinant of nonobviousness — is someone in the same technical field as the inventor, at a common skill level.[38] "Common" here means that the PHOSITA possesses a level of skill that is the median of all those in the same technical field.[39] It does not mean that the PHOSITA is at the same level as the inventor, who might in fact possess an extraordinary level of skill.[40] In determining the relevant median skill level, courts take into account multiple factors. Such factors include the techniques and methods in the prior art, the sophistication of the technology involved, and the typical level of education of practitioners in the field.[41] Furthermore, unlike any individual in the field, the PHOSITA is "endowed with knowledge of all of the relevant prior art references."[42] Thus, a PHOSITA represents an objective legal standard for patentability, akin to the reasonably prudent person in tort law.[43]

Prior art — the second determinant — contributes to this objective determination by physically demonstrating the degree to which the invention represents a nontrivial improvement over itself.[44] Taken together, the PHOSITA sets the standard for the court to objectively compare the invention with the prior art.[45] This is because, as mentioned above, a PHOSITA represents someone with the knowledge of all prior art that is relevant.[46] The court's role is to determine if a PHOSITA could have used their skills, knowledge, and intuition to combine elements from prior art to create the invention.[47] If the court determines that a PHOSITA would have been inspired to create the invention in the first place, then it is obvious and unpatentable.[48]

In summary, a PHOSITA is set up as an extrinsic source of factual determination to assist the court — the decision-maker — to

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[38] Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1189 (2002) [hereinafter *Technology-Specific*].

[39] *Id.*

[40] *Id.*

[41] *Id.*

[42] *Id.* at 1188.

[43] *Id.* at 1187-88.

[44] *See* Petherbridge, *supra* note 17, at 914. Note that here, "itself" refers to the prior art.

[45] *See id.*

[46] Burk & Lemley, *Technology-Specific, supra* note 38, at 1188.

[47] *See id.* at 1187.

[48] *See* Petherbridge, *supra* note 17, at 914.

formulate an argument for nonobviousness.[49] The court determines if the invention would have been obvious to a PHOSITA at the time it was invented, with reference to all relevant prior art.[50] In this way, the court is discouraged from making decisions "based on unarticulated shadow rationales and . . . analytical corner cutting that can lead to error."[51]

Since a nonobviousness determination is based on an objective framework, it stands to reason that it would benefit from the Federal Circuit's TSM test. This is because the TSM test is also objective, and a standardized application of the TSM test promotes procedural and precedential certainty.[52] However, the Supreme Court took issue with the Federal Circuit's rigid application of the TSM test, and it granted certiorari in *KSR* to express its disapproval.[53]

B. KSR Int'l Co. v. Teleflex Inc.

In *KSR*, respondents Teleflex Inc. ("Teleflex") had patented a position-adjustable pedal assembly with an electronic position sensor for automotive vehicles.[54] Petitioner KSR International Co. ("KSR") subsequently developed a similar adjustable pedal system for cars and obtained a patent for the design as well.[55] Teleflex brought suit in the Eastern District of Michigan accusing KSR of infringing their patent, and the district court granted KSR summary judgment.[56] The district court determined that KSR had satisfied the TSM test because the prior art taught this particular solution to an existing problem.[57] The Federal Circuit subsequently reversed, ruling that the district court had not applied the TSM test strictly enough.[58] The Federal Circuit held that the district court had failed to make specific findings as to what in the prior art would have motivated a PHOSITA to try Teleflex's combination.[59] Furthermore, the Federal Circuit explained,

[49] *Id.*
[50] Burk & Lemley, *Technology-Specific, supra* note 38, at 1186-88.
[51] Petherbridge, *supra* note 17, at 914.
[52] *See id.*
[53] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 407, 415 (2007).
[54] *Id.* at 406.
[55] *Id.* at 410.
[56] *Id.* at 412.
[57] *Id.* at 413.
[58] *Id.*
[59] *Id.* at 413-15.

the prior art was not designed to solve the problem that Teleflex solved, and thus did not "teach" Teleflex the solution.[60]

Up to the point of the *KSR* case, the Federal Circuit had been consistently applying the TSM test in its obviousness jurisprudence.[61] Notwithstanding the Federal Circuit's contemporaneous concessions on the flexibility of the TSM test,[62] the Supreme Court decided to put its foot down with *KSR*. The Supreme Court used *KSR* to foreclose any further rigid and mandatory application of TSM incompatible with its own precedents on the obviousness question.[63] In particular, the Court objected to the Federal Circuit's focus on "precise teachings directed to the specific subject matter."[64] Instead, the Court espoused an approach taking into account the "inferences and creative steps" that a PHOSITA would employ.[65] Drawing upon a number of its own precedential decisions,[66] the Supreme Court emphasized the need to take an expansive and flexible approach and pursue a broad inquiry into obviousness.[67]

To be sure, the Supreme Court did not reject the TSM test outright.[68] Rather, it rejected the Federal Circuit's narrow focus and rigid application of the TSM test in its obviousness inquiry.[69] This signaled the possibility that the Supreme Court was allowing the Federal Circuit to continue applying the TSM test, but under a broader

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[60] *Id.* at 414-15.

[61] *See* Petherbridge, *supra* note 17, at 911-12, 914.

[62] *See, e.g.*, DyStar Testilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1367 (Fed. Cir. 2006) ("Our suggestion test is . . . quite flexible . . . ."); Alza Corp. v. Mylan Labs. Inc., 464 F.3d 1286, 1291 (Fed. Cir. 2006) ("There is flexibility in our obviousness jurisprudence . . . .").

[63] *KSR*, 550 U.S. at 419.

[64] *Id.* at 418.

[65] *Id.*

[66] The most important of which was the seminal case *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), exhorting courts to look at secondary considerations that might be instructive. *Id.* at 17-18. The Court in *KSR* also cited Sakraida v. Ag Pro, Inc., 425 U.S. 273, 282 (1976) (holding that a combination of elements yielding no more than the sum of its parts is obvious); United States v. Adams, 383 U.S. 39, 50-52 (1966) (holding that a substitution of one element for another known in the field is obvious if it yields a predictable result); Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152-53 (1950) (holding that a combination of existing elements with no resultant change in their combined functions is obvious).

[67] *KSR*, 550 U.S. at 415-18.

[68] The Court stated that the TSM test itself gave "helpful insight" into the obviousness inquiry and was not inconsistent with the Court's previous decisions. *Id.* at 418-19.

[69] *Id.* at 419.

and more flexible approach.[70] However, in reality, *KSR* caused the Federal Circuit to largely abandon any explicit and formalistic application of the TSM test.[71] In fact, five years after *KSR*, the Federal Circuit made a formalistic reference to TSM in fewer than five percent of its opinions where it was making an obviousness determination.[72] In contrast, the Federal Circuit had applied a formalistic TSM test in about thirty percent of its opinions in the very year (but before) the Supreme Court decided *KSR*.[73] Evidently, *KSR* had sounded a death knell for the Federal Circuit's TSM test.

C. Expanding the Role of the PHOSITA

With broad strokes, the Supreme Court outlined two basic principles in *KSR*, both involving the PHOSITA's central role in the obviousness determination.[74] First, the proper question is whether the combination of elements of prior art is obvious to the PHOSITA, not the patentee.[75] The reasoning behind this was that the problem motivating a particular patentee may be just one of many that the patent's subject matter addresses.[76] An invention can be obvious even if it solves a problem in a field that is different from the one its component parts (prior art) were designed for.[77] It is obvious if this combination of prior art elements using known methods is nothing more than a predictable result.[78] This expanded the scope of prior art a court could consider in its determination.[79] In effect, a PHOSITA is given the freedom to consider prior art from beyond the narrow scope of the patent's subject matter.[80] A PHOSITA may thus extrapolate the usefulness of prior art from one field of technology to another.[81]

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[70] *See* Jason Rantanen, *The Federal Circuit's New Obviousness Jurisprudence: An Empirical Study*, 16 STAN. TECH. L. REV. 709, 721-22 (2013).

[71] *See id.* at 752-57 (examining cases post-*KSR* up until 2013).

[72] *Id.* at 756.

[73] *Id.*

[74] *KSR*, 550 U.S. at 417-21.

[75] *Id.* at 420.

[76] *Id.*

[77] *See id.* at 420-21.

[78] *See id.* at 416-17 (referencing the Court's previous opinions in Sakraida v. Ag Pro, Inc., 425 U.S. 273, 282 (1976); Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 60-62 (1969); United States v. Adams, 383 U.S. 39, 50-52 (1966); Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152-53 (1950)).

[79] Rogers, *supra* note 26, at 62.

[80] *See KSR*, 550 U.S. at 420-21.

[81] *See id.*

Second, the Supreme Court expanded the scope of determination of whether a combination of prior art was "[o]bvious to try."[82] The Court explained that a design need or market pressure may lead a PHOSITA to successfully solve a problem using an array of finite predictable solutions.[83] However, this is then the product of ordinary skill and common sense, not innovation.[84] Here, the success that a PHOSITA has in solving the problem is not restricted to what the PHOSITA would have been able to predict in advance.[85] This is because a PHOSITA has good reason to pursue known options within their technical knowledge.[86] This factor opens the door for finding obviousness where the results of a particular combination were not known in advance by the inventor but could have been predicted by a PHOSITA.[87]

Overall, *KSR* has brought the role of the PHOSITA to the forefront of the obviousness analysis.[88] The holding in *KSR* stated that courts can take into account any "inferences and creative steps" a PHOSITA might utilize.[89] Importantly, this has expanded the role of the PHOSITA.[90] A PHOSITA can now use their own common sense and creativity to define the scope of prior art and determine whether a solution is obvious to try.[91]

A subsidiary effect of *KSR* is that the Supreme Court rejected the Federal Circuit's position that distortion from hindsight bias must be fervently guarded against.[92] Similarly, the Court rejected the opinion that the best defense against hindsight bias is a rigorous application of the TSM test.[93] This similarly gives the PHOSITA more freedom and

[82] *Id.* at 421 (alteration in original) (citation omitted).

[83] *Id.*

[84] *Id.* Here, the Court drew from its own previous opinions. *Id.* at 415-17 (citing Sakraida v. Ag Pro, Inc., 425 U.S. 273, 282 (1976) (stating that combining old elements to produce no more than the sum of their functions is obvious to try); Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 60-62 (1969) (same); United States v. Adams, 383 U.S. 39, 50-52 (1966) (finding that substitution of one element for another known in the field, yielding predictable results, is obvious to try)).

[85] Rogers, *supra* note 26, at 65.

[86] *Id.* at 63 (quoting *KSR*, 550 U.S. at 421).

[87] *Id.* at 65.

[88] *See id.*

[89] *KSR*, 550 U.S. at 418.

[90] Rogers, *supra* note 26, at 65-66.

[91] *Id.*

[92] *See KSR*, 550 U.S. at 421; *infra* Part II.A (discussing the hindsight bias and its potential impact on the obviousness determination).

[93] *KSR*, 550 U.S. at 421; *see also In re* Dembiczak, 175 F.3d 994, 998-99 (Fed. Cir.

authority in drawing from their own skill set and experience to define what is obvious.[94]

Finally, the Supreme Court reemphasized its seminal holding in *Graham v. John Deere Co. of Kansas City*.[95] The Court stated that secondary considerations such as commercial success and long felt but unsolved needs may be considered in the nonobviousness analysis.[96] This truly broadened the scope of what courts could utilize in determining nonobviousness, giving courts access to whatever a PHOSITA would reasonably consider relevant to their own field of expertise.[97]

II. FEDERAL CIRCUIT JURISPRUDENCE ON NONOBVIOUSNESS FOLLOWING KSR HAS IMPAIRED LOWER TRIBUNALS

A. The Federal Circuit Has Been Inconsistent in Applying KSR Principles

While the Supreme Court clearly rejected any rigid application of the TSM test, it left open the issue of how courts were to apply the principles of *KSR*.[98] As noted in Part I.B, the Court did not reject the TSM test itself, finding no necessary inconsistency between it and the Court's own precedent.[99] This is not surprising, given the Court's strong emphasis on taking an "expansive and flexible approach" to determining obviousness.[100] This result quickly resonated down the echelons to the U.S. Patent and Trademark Office ("USPTO").[101] In October 2007, the USPTO issued revised guidelines to patent

1999) (stating that "[c]lose adherence to [TSM] methodology is especially important" so that the court does not "fall victim to the insidious effect of a hindsight syndrome" (quoting W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed.Cir.1983))).

94 *See* Rogers, *supra* note 26, at 66.

95 Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966).

96 *KSR*, 550 U.S. at 406 (quoting *Graham*, 383 U.S. at 17-18).

97 *See* Rogers, *supra* note 26, at 65-66.

98 *See* Ashley Houston, KSR International Co. v. Teleflex Inc.*: The Supreme Court Declines the Opportunity to Finally Set the Record Straight and Articulate One Clear Standard for Determining Obviousness in Patent Cases*, 4 J. BUS. & TECH. L. 219, 219 (2008).

99 *KSR*, 550 U.S. at 419.

100 *Id.* at 415.

101 *See* Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57,526, 57,526 (Oct. 10, 2007).

examiners for determining obviousness after *KSR*.[102] Following these revised guidelines, an examiner no longer needs to locate a TSM to combine from the prior art.[103] This means that an examiner is given greater discretion in deciding whether an invention is obvious.[104] As also noted in Part I.B, the Federal Circuit responded to *KSR* by discarding any formalistic reference to the TSM test in its opinions.[105] The Federal Circuit has forsworn the TSM test to the extent that fewer than five percent of its opinions contain any explicit mention of it at the end of 2012.[106] In terms of practical effect, the Federal Circuit reached a final determination of obviousness ten percent more frequently after the *KSR* decision.[107]

However, what has the effect of *KSR* been on the actual jurisprudence of the Federal Circuit in nonobviousness cases? The Federal Circuit's legal reasoning has unfortunately run the gamut from stretching *KSR*'s flexibility to its limit[108] to outright defiance against *KSR* by completely ignoring it as precedent.[109] Two representative patent suit cases involving biochem technologies — *In re Kubin*[110] and *Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*[111] — illustrate these extremes.

In *Kubin*, the Federal Circuit disapproved of one of its own former decisions, *In re Deuel*.[112] Here, the Federal Circuit found a patent claim for an isolated DNA sequence (as a pharmaceutical product) obvious to try and therefore unpatentable.[113] In this case, prior art did not explicitly supply the particular DNA sequence in the challenged patent

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[102] *Id.*

[103] Nicholas Angelocci, KSR v. Teleflex*: Obvious Ambiguity*, 18 DEPAUL J. ART, TECH. & INTELL. PROP. L. 293, 317 (2008).

[104] *Id.*

[105] Rantanen, *supra* note 70, at 752-57.

[106] *Id.* at 756.

[107] *Id.* at 751. More specifically, over the period of five years after *KSR* was announced, the Federal Circuit reached a final determination of obviousness ten percent more frequently than during the ten-year period pre-*KSR*. *Id.*

[108] *See In re* Kubin, 561 F.3d 1351, 1360-61 (Fed. Cir. 2009).

[109] *See* Pfizer Inc. v. Teva Pharm. USA, Inc., 555 F. App'x 961, 968-70 (Fed. Cir. 2014).

[110] *Kubin*, 561 F.3d 1351.

[111] *Pfizer*, 555 F. App'x 961.

[112] *Kubin*, 561 F.3d at 1358-59 (citing *In re* Deuel, 51 F.3d 1552, 1558-59 (Fed. Cir. 1995) (finding a patent claim nonobvious because the inventor had no advance knowledge of the result of combining known elements)).

[113] *Id.* at 1361.

claim.[114] However, because PHOSITAs testified that they had "every motivation" to achieve that result and "every reasonable expectation of success," the claimed invention was obvious to try.[115] *Kubin* skirted the limits of *KSR* in its conclusion. The court concluded the invention was obvious even though the inventors did not predict the result, but had the knowledge and skill to discover it.[116] This decision was not inconsistent with *KSR*, but pushed the boundary for what is obvious to try.[117] In *KSR*, the Supreme Court hinted at but did not make an explicit recommendation for how to deal with a situation like this.[118]

On the other end of the spectrum, the Federal Circuit completely snubbed *KSR* in its decision in *Pfizer*.[119] In its published opinion, the Federal Circuit completely neglected to cite *KSR*, and in fact cited only one oblique Supreme Court case pertaining to obviousness.[120] Instead, the Federal Circuit upheld a finding of nonobviousness for Pfizer's small-molecule drug compound.[121] It did so by applying a strict TSM analysis as well as a pre-*KSR* Federal Circuit obviousness test that does not conform to *KSR*.[122] In other words, the Federal Circuit

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114 *Id.*

115 *Id.* (citation omitted).

116 *See id.*

117 Joanne Kwan, *A Nail in the Coffin for Gene Patents*, 25 BERKELEY TECH. L.J. 9, 24-26 (2010).

118 *See* Rogers, *supra* note 26, at 65.

119 *See* Pfizer Inc. v. Teva Pharm. USA, Inc., 555 F. App'x 961, 968-70 (Fed. Cir. 2014).

120 *Id.* at 968-69 (citing Microsoft Corp. v. i4i L.P., 564 U.S. 91, 95, 96 (2011)).

121 *Id.* at 969.

122 *See id.* at 968-70 (referencing the pre-*KSR* test from Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., 471 F.3d 1369, 1378 (Fed. Cir. 2006)). Here, the Federal Circuit flouted the Supreme Court's obvious-to-try standard, because all Pfizer did was replace an alkyl group on the previously-patented amino acid 3-isopropyl-GABA with a slightly bulkier one (from isopropyl to isobutyl) to produce another compound with similar anticonvulsive properties. This is a known technique in drug discovery. *See, e.g.*, Nicholas A. Meanwell, *Synopsis of Some Recent Tactical Application of Bioisosteres in Drug Design*, 54 J. MED. CHEM. 2529, 2539 & tbl.15 (2011) (showing that replacing an isopropyl group with an isobutyl group results in no significant change in potency, metabolic stability (in the human liver), and cell permeability for an antiviral drug). Furthermore, with such a slight change in molecular mass and no new electron-donating/withdrawing groups, the physiological effect of the drug is unlikely to change. *But see* Heike Schönherr & Tim Cernak, *Profound Methyl Effects in Drug Discovery and a Call for New C-H Methylation Reactions*, 52 ANGEWANDTE CHEMIE 12256, 12257-61 (2013) (Ger.) (stating that the addition of a methyl group (which is what Pfizer did here) increases the binding affinity, and therefore the efficacy, of the drug).

backpedaled all the way to pre-*KSR* jurisprudence and defied the Supreme Court's explicit instruction not to apply a rigid TSM test.[123]

Scholars have pointed to one major reason that the Federal Circuit has resisted establishing a clear nonobviousness standard comporting with *KSR* for so many years.[124] Fear of hindsight bias, which the Supreme Court addressed in *KSR*, has continued to make the Federal Circuit unwilling to adopt a flexible *KSR* approach.[125] Empirical studies have demonstrated that once jurors are aware of an invention, they are much more likely to decide that the invention would have been obvious.[126] This hindsight bias skews obviousness litigation, because a decision maker might use hindsight reconstruction to choose prior art to deprecate a claimed invention.[127] In *KSR*, the Supreme Court admonished the Federal Circuit for overemphasizing the risk that courts would fall prey to hindsight bias.[128] The Court faulted the Federal Circuit for applying rigid preventative rules to combat such questionably relevant bias, because it "den[ied] factfinders recourse to common sense."[129]

Historically, the Federal Circuit has always been greatly concerned about hindsight bias affecting a nonobviousness determination.[130] However, the statutory text calls for an examination of whether an invention was obvious to a PHOSITA at some earlier date before any litigation commenced.[131] This necessitates a backward-looking analysis, which is invariably accompanied by hindsight.[132] Such hindsight analysis tends to lead to hindsight bias.[133] This is because once an invention is known, an examiner often "exaggerate[s] what could have been anticipated in foresight and . . . tend[s] to view the invention as inevitable."[134] Thus, even after *KSR*, the Federal Circuit

123 Rogers, *supra* note 26, at 70.

124 *See* Angelocci, *supra* note 103, at 320; Rogers, *supra* note 26, at 90-95.

125 *See* Rogers, *supra* note 26, at 90-91 ("Fear of hindsight bias has been a significant factor in the Federal Circuit's use of its obviousness test for new pharmaceutical compounds.").

126 Ashley Allman Bolt, *Combating Hindsight Reconstruction in Patent Prosecution*, 64 EMORY L.J. 1137, 1139 (2015); Mandel, *Patently Non-Obvious*, *supra* note 25, at 1451.

127 Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1371 (Fed. Cir. 2000).

128 *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

129 *Id.*

130 Rogers, *supra* note 26, at 90.

131 *Id.*; *see also* 35 U.S.C. § 103 (2018).

132 Rogers, *supra* note 26, at 90.

133 Gregory Mandel, *Patently Non-Obvious II: Experimental Study on the Hindsight Issue Before the Supreme Court in* KSR v. Teleflex, 9 YALE J.L. & TECH. 1, 3 (2007).

134 *Id.*

has continued to allow a perceived concern over hindsight bias to guide their decisions on nonobviousness.[135]

Despite this, district courts, the PTAB, and the USPTO still have to look towards the Federal Circuit for guidance, for the following reasons. First, the Supreme Court explicated a flexible approach to the nonobviousness analysis.[136] Second, and more importantly, *KSR* only dealt with a patent for a vehicle pedal assembly,[137] classified as a mechanical technology.[138] The *Kubin* and *Pfizer* Federal Circuit cases on the other hand dealt with DNA and small-molecule drugs, classified as biological and chemical technologies respectively.[139] This might not amount to an intra-circuit split because the cases did not technically disagree in their respective tests for obviousness.[140] However, conflicting signals by the Federal Circuit will throw the patent sphere into disarray, and courts will no longer have consistent precedential guidance to make decisive findings.[141] Conflicting jurisprudence or outright defiance by the Federal Circuit will have a negative effect on lower tribunals and prevent the development of a consistent *KSR* standard.[142]

B. The Federal Circuit Has No Clear-Cut Fact-Finding Standards for Biochem Technologies

Obviousness under the Patent Act is a legal conclusion, but it is a conclusion based on factual inquiries, including a PHOSITA's expert

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[135] *See, e.g.*, Pfizer Inc. v. Teva Pharm. USA, Inc., 555 F. App'x 961, 970 (Fed. Cir. 2014) ("A patent challenger . . . must demonstrate the selection of a lead compound based on its 'promising useful properties,' not a hindsight-driven search for structurally similar compounds." (quoting Daiichi Sankyo Co. v. Matrix Labs., Ltd., 619 F.3d 1346, 1354 (Fed. Cir. 2010))); Eurand, Inc. v. Myland Pharm., Inc. (*In re* Cyclobenzaprine Hyrdrochloride Extended-Release Capsule Patent Litig.), 676 F.3d 1063, 1079 (Fed. Cir. 2012) ("'[J]udicial hunches' are encouraged by hindsight bias."); Otsuka Pharm. Co. v. Sandoz, Inc., 678 F.3d 1280, 1296 (Fed. Cir. 2012) ("The inventor's own path itself never leads to a conclusion of obviousness; that is hindsight.").

[136] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415 (2007).

[137] *Id.* at 405.

[138] *See* Rantanen, *supra* note 70, at 747.

[139] *See id.* at 747-48, 748 n. 159.

[140] *See* Rogers, *supra* note 26, at 67, 72 (stating that in both *Kubin* and *Pfizer*, the Federal Circuit considered what "the prior art teaches" and some sort of "motivation" to pursue the invention).

[141] *See* Angelocci, *supra* note 103, at 317.

[142] *See id.* at 318 (although here the author additionally argues that the Supreme Court should not have rejected the TSM standard in the first place); Rantanen, *supra* note 70, at 764.

testimony.[143] The Federal Circuit accords deference to trial tribunals with respect to fact-finding on a standard of clear error.[144] Of course, because the ultimate determination is a question of law, the Federal Circuit does not have to accord any deference to a trial tribunal's opinion (including its findings of fact) upon a challenge of legal error.[145] However, empirical evidence post-*KSR* suggests that the Federal Circuit has been granting greater deference to lower tribunals on determinations of obviousness based on fact-finding.[146] Thus, it has now become more important at the trial court level to adduce adequate facts.[147] This will ensure that the judgment is not disturbed upon appeal.[148] In addition, presenting a set of accurate and sufficient facts on appeal allows the Federal Circuit to efficiently make binding determinations.[149]

Some scholars have bemoaned the Supreme Court's failure in *KSR* to provide a clear-cut principle to apply a nonobviousness analysis.[150] In addition, even before *KSR*, scholars had already noted prominent divergences in the way that the Federal Circuit had applied patent law to different types of technologies.[151] For instance, the Federal Circuit

[143] *See, e.g.*, KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007); Pfizer Inc. v. Teva Pharm. USA, Inc., 555 F. App'x 961, 968 (Fed. Cir. 2014); *In re* Kubin, 561 F.3d 1351, 1355 (Fed. Cir. 2009).

[144] Millennium Pharm., Inc. v. Sandoz Inc., 862 F.3d 1356, 1363-64 (Fed. Cir. 2017); Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc., 752 F.3d 967, 978 (Fed. Cir. 2014).

[145] *See* Kevin Casey et al., *Standards of Appellate Review in the Federal Circuit: Substance and Semantics*, 11 FED. CIR. B.J. 279, 282 (2001-2002). This issue also arises in appeals of patent interference rulings, review of which is again *de novo* and therefore without deference. PAUL M. COLTOFF ET AL., 26 FED. PROC., L. ED. § 60:556 (2019).

[146] Rantanen, *supra* note 70, at 742-45.

[147] *See id.* at 745-46, 746 n.153.

[148] *See id.* at 745-47.

[149] *See id.*

[150] Angelocci, *supra* note 103, at 293 ("The Court failed to . . . provide guidance to the lower courts . . . instead providing for future ambiguity in determining the obviousness question."); Houston, *supra* note 98, at 219 ("[T]he Court implemented an unworkable standard . . . .").

[151] *See, e.g.*, Burk & Lemley, *Technology-Specific*, *supra* note 38, at 1183-85; Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 633 (1998); Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1253-54 (2000); Robert A. Hodges, Note, *Black Box Biotech Inventions: When a "Mere Wish or Plan" Should be Considered an Adequate Description of the Invention*, 17 GA. ST. U. L. REV. 831, 833 (2001).

favored finding biochem inventions nonobvious as compared to software inventions, despite prior art evidencing the contrary.[152] In contrast, the Federal Circuit imposed much more stringent enablement and written description requirements on biochem inventions than software inventions.[153] Any added uncertainty the Supreme Court caused in the way it decided *KSR* could result in further inconsistent decision-making in lower tribunals.[154]

Thus, establishing a more standardized approach to nonobviousness seems like a prudent course to take, given the lack of clarity in *KSR*.[155] First, as scholars have noted, patent law is generally a unitary system, designed to be applied neutrally to different technologies.[156] Thus, logically speaking, the Federal Circuit should follow the general standards of section 103, *Graham* and *KSR* in determining obviousness for all inventions.[157] In doing so, the Federal Circuit would remain faithful to the gatekeeping function of patent law.[158] Additionally, district courts can universally apply a workable, standardized analysis, precluding the need for district court judges to become experts at nonobviousness jurisprudence.[159] This approach might thus also lower the risk of concentrating patent litigation in a handful of courts seen as better equipped to adjudicate nonobviousness cases.[160]

Second, the uncertainty of *KSR* might prove detrimental to the patent world in the long run, and standardizing the nonobviousness

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[152] Burk & Lemley, *Technology-Specific*, *supra* note 38, at 1156.

[153] *Id.*

[154] Angelocci, *supra* note 103, at 318; Rantanen, *supra* note 70, at 764.

[155] *See* Angelocci, *supra* note 103, at 323.

[156] *See* Burk & Lemley, *Technology-Specific*, *supra* note 38, at 1157 (noting a "nominally unitary patent system"); Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. Rev. 51, 101 (2010) (observing that the patent system is supposed to "apply and develop seemingly neutral principles to divergent industries").

[157] Rogers, *supra* note 26, at 105.

[158] *Id.*

[159] *See* Burk & Lemley, *Technology-Specific*, *supra* note 38, at 1188 (stating that one practical effect of having a PHOSITA is that that judges and other arbiters of patentability are not required to be experts in a given field).

[160] *Cf.* TC Heartland LLC v. Kraft Foods Grp. Brands, 137 S. Ct. 1514, 1516-17 (2017) (ruling that "a domestic corporation 'resides' only in its State of incorporation for purposes of the patent venue statute"); Ron Abrams, *Supreme Court Decision Deals Blow to "Patent Trolls" and the "Best Little" East Texas Towns That Thrive on Patent Litigation*, IPWATCHDOG (June 11, 2017), http://www.ipwatchdog.com/2017/06/11/supreme-court-blow-patent-trolls-east-texas-towns-patent-litigation/ (detailing how the Supreme Court effectively curtailed "patent trolls" from continuing to use the forum that was friendliest to them — the Eastern District of Texas — in *TC Heartland LLC v. Kraft Foods Group Brands*).

test would alleviate such negative effects.[161] Each patent application can cost an inventor tens of thousands of dollars.[162] Previously, the Federal Circuit's stable TSM test gave inventors and attorneys a predictable test to evaluate whether to pursue a patent application.[163] However, *KSR* did not explicitly spell out workable principles, and the Federal Circuit has become even more unpredictable in its nonobviousness jurisprudence.[164] Inventors might begin to view patent applications as high-risk investments, because they think the likelihood of obtaining a patent is unclear and unpredictable.[165] Because of this, inventors might have much less of an incentive to research and create, resulting in fewer beneficial products becoming available to the public.[166] Alternatively, an inventor may choose a different method of securing an exclusive right to their technology, such as by keeping it a trade secret.[167] In contrast to a patented invention, a trade secret is kept completely hidden from the public.[168] Thus, society derives no benefits from the invention, because no one can work or improve on it.[169] An additional risk is that someone else might discover the same invention at a later date. If this happens, the original inventor will not have the legal right to prevent this person from profiting off of it.[170] These are strong arguments for having the Federal Circuit develop a standard test to resolve the ambiguity of *KSR*.[171]

However, any divergence in the way the Federal Circuit treats different technologies[172] does not necessarily amount to an inconsistent application of patent law. One should also not conclude that the Federal Circuit has to develop a uniform test for nonobviousness. There should not be a one-size-fits-all approach to the nonobviousness analysis because such an approach does not take into consideration

161 *See* Angelocci, *supra* note 103, at 314-15, 321-23; Rantanen, *supra* note 70, at 762-63.

162 Angelocci, *supra* note 103, at 315.

163 *Id.*

164 Angelocci, *supra* note 103, at 317-18; *supra* Part II.A.

165 Angelocci, *supra* note 103, at 315.

166 *See id.*

167 *Id.* at 321.

168 *Id.*

169 *Id.*

170 *See id.* at 321-22.

171 *Id.* at 314-15, 322-23.

172 *E.g.*, Burk & Lemley, *Technology-Specific*, *supra* note 38, at 1183-85; Mueller, *supra* note 151, at 633; Sampson, *supra* note 151, at 1253-54; Hodges, *supra* note 151, at 831-33.

substantial differences amongst the underlying technologies.[173] Furthermore, the Supreme Court in *KSR* explicitly emphasized the need for an expansive and flexible approach in analyzing obviousness.[174] This flexible approach would allow for biochem technologies to be treated differently from mechanical and electronic technologies,[175] while still conforming to the principles of *KSR*.

Biochem technologies, the largest source of patents granted in the pharmaceutical industry, are driven by similar research, development, testing, and market concerns.[176] Biochem technologies should be treated differently from the other technologies because they are "unpredictable arts,"[177] as opposed to mechanical technologies, which are "predictable arts."[178] For the predictable arts, an invention is generally the sum of its parts.[179] Even a layperson might be able to predict the overall function of an invention given its components.[180] For the unpredictable arts, however, combining known prior arts with known properties might not yield a product with the expected sum of their properties.[181] Because of this, a nonobviousness determination for biochem technologies necessarily involves examination of prior art that only a PHOSITA would be familiar with.[182] It is likely that only a PHOSITA would be able to explain to a layperson the functions of the

[173] One view is that the "directional rules provided by *KSR* . . . may be a poor fit when applied to . . . more complex technologies" such as pharmaceuticals. Rantanen, *supra* note 70, at 763. However, this observation might not be accurate given that the Supreme Court clearly meant to provide flexible guidelines that should be adaptable to any technology. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415 (2007).

[174] *KSR*, 550 U.S. at 415.

[175] This categorical treatment of technologies is common and well-known. *See, e.g.*, Rantanen, *supra* note 70, at 747-51. Software would fall under the category of "electronic" technology. *Id.* at 748 n. 161.

[176] *See generally* Ethan A. Halm & Annetine C. Gelijns, *An Introduction to the Changing Economics of Technological Innovation in Medicine*, *in* 2 MEDICAL INNOVATION AT THE CROSSROADS 1, 3-6 (Ethan A. Halm & Annetine C. Gelijns eds., 1991); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1584, 1588 (2003) [hereinafter *Policy Levers*].

[177] *See* Pharm. Res., Inc. v. Roxane Lab., Inc., 253 F. App'x 26, 28-29 (Fed. Cir. 2007).

[178] *See* Rantanen, *supra* note 70, at 747-48. Electronic technologies would belong somewhere in the middle ground between predictable and unpredictable. *See id.* at 747.

[179] *See id.*

[180] *See id.*

[181] *See id.* at 747-48.

[182] *See* Burk & Lemley, *Technology-Specific, supra* note 38, at 1187. Here by "only" I mean that a PHOSITA is the basis for determining who would understand the technology. Of course, anyone in the same field with a higher level of skill than a PHOSITA should similarly have the requisite understanding and familiarity.

prior art.[183] Notably, even a PHOSITA might not be able to fully predict the outcome of combining known biochem prior art, further complicating the nonobviousness analysis.[184]

The distinction between biochem and other technologies thus exists on two levels: the level of sophistication of the user of the prior art[185] and the level of sophistication of the prior art itself.[186] Biochem technologies can be more sophisticated and unpredictable than other technologies, requiring a PHOSITA to have a concomitantly higher level of understanding in the relevant field.[187] Regardless of the technology involved — biochem, mechanical, or electronic — all patent claims are subject to the requirements of the Patent Act.[188] However, it would be unwieldy and disingenuous to attempt to force them to conform to a uniform formulation of the law.[189] It would be more objective and sensible to allow a PHOSITA to inform the courts of what is considered obvious to a median member of that biochem field.[190] One can make even finer PHOSITA distinctions, for instance distinguishing between PHOSITAs for organic chemistry and materials chemistry.[191] This would be important for determining not only the level, but also the specific type of expertise required for a PHOSITA.[192] A careful determination of the relevant PHOSITA and prior art would then allow the Federal Circuit to make an ultimate conclusion of law based on sufficient and relevant evidence.[193]

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183 *See id.* at 1187-88; Rogers, *supra* note 26, at 95-96.

184 *See* Rantanen, *supra* note 70, at 747-48; Rogers, *supra* note 26, at 66.

185 *See* Rantanen, *supra* note, at 747-48; Rogers, *supra* note 26, at 96.

186 As an analogy, compare a piece of Ikea furniture with an RNA sequence used in CRISPR/Cas9. The former is a tangible, visible object whose function and method of assembly would be fairly obvious to most (after reading the instructions provided). The latter is a string of nucleotides invisible to the naked eye, requiring advanced scientific methods to produce, purify, and observe. Without the decades of research that have gone into it, people would not even know how to use it, or what to use it for.

187 *See* Rantanen, *supra* note, at 747-48; Rogers, *supra* note 26, at 96.

188 35 U.S.C. § 101 (2018) ("Whoever invents or discovers *any* new and useful process . . . .") (emphasis added).

189 *See* Rogers, *supra* note 26, at 95-96.

190 *See id.*

191 *Cf. Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256-57 (Fed. Cir. 2007) (distinguishing between an otolaryngologist and a pediatrician as the PHOSITA relevant to factual inquiry).

192 *See id.*

193 *See* Burk & Lemley, *Technology-Specific*, *supra* note 38, at 1188.

C. The Federal Circuit Has Failed to Accord the PHOSITA the Level of Importance KSR Requires

The PHOSITA plays a central role in calibrating the legal standard for obviousness[194] as codified in the Patent Act.[195] However, prior to *KSR*, the Federal Circuit limited the role of the PHOSITA to defining only the "scope, content and meaning" of prior art."[196] The Federal Circuit did not consult the PHOSITA on the determinative question of whether an invention was nonobvious in consideration of such prior art.[197] Even worse, the Federal Circuit sometimes approximated the knowledge of the PHOSITA with that of an examiner from the USPTO.[198] In *KSR*, the Supreme Court attempted to steer the Federal Circuit back onto the proper statutory path. The Court reemphasized the importance of the PHOSITA's viewpoint in determining what is obvious to try.[199]

A PHOSITA contributes to determining whether an invention is nonobvious in two distinct ways. First, the PHOSITA defines the scope and content of prior art relevant to the invention.[200] Second, the PHOSITA provides the level of ordinary skill that is relevant in determining what is obvious to try.[201] The importance of the first factor is fairly straightforward. From *KSR*, the Federal Circuit incorrectly assumed that a PHOSITA should only look to prior art designed to solve the same problem as the disputed patent.[202] This approach failed to account for the fact that an inventor could recognize that prior art has obvious uses beyond its primary function.[203] Thus, an inventor could have combined prior art to solve a problem not addressed by the primary functions of the component parts.[204] The Federal Circuit's approach severely limited the scope of prior art that a PHOSITA could consider.[205] In *KSR*, the Supreme Court explained that a PHOSITA may consider any and all prior art

194 *Id.* at 1185-86.

195 35 U.S.C. § 103 (2018) ("[O]bvious . . . to a person having ordinary skill in the art . . . .").

196 Rogers, *supra* note 26, at 95.

197 *Id.*

198 Burk & Lemley, *Technology-Specific*, *supra* note 38, at 1187.

199 KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 420-21 (2007).

200 *See id.* at 420; Rogers, *supra* note 26, at 62.

201 *See KSR*, 550 U.S. at 420-21; Rogers, *supra* note 26, at 65.

202 *KSR*, 550 U.S. at 420.

203 *Id.*

204 *Id.*

205 *See id.* at 420-21.

that they viewed as relevant to the invention's subject matter.[206] This effectively broadened the scope of what the disputed invention could be compared with, as compared to the Federal Circuit's restrictive standards.[207]

The second factor — the level of ordinary skill of the PHOSITA — serves as an objective median standard for the court to measure obviousness.[208] It is an "external metric, rather than . . . an expectation based on . . . the skill of the [actual] inventor."[209] This objective standard also has the practical effect of not requiring Federal Circuit judges to learn the subject matter and become experts in the field.[210] However, the Supreme Court had not explicated in *KSR* the factors that courts should consider in choosing someone of "ordinary skill."[211] In fact, one scholar has hyperbolically asserted that the Supreme Court has never in history given courts any insight into what constitutes a PHOSITA.[212] After *KSR*, the Federal Circuit provided a list of factors relevant to determining the skill of a PHOSITA in *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*[213] The factors on this nonexhaustive list include: rapidity with which innovations are made, sophistication of the technology, and educational level of active workers in the field.[214] Even with such factors named explicitly, variation and uncertainty still exist in determining sophistication and median educational level.[215]

The factors above are ostensibly aimed at providing adequate levels of fact-finding required for courts to reach sound legal conclusions.[216] PHOSITAs provide these facts to the court, but their contributions to a nonobviousness determination are not limited to their skill and educational level.[217] PHOSITAs also contribute their judgment, intuition, and tacit knowledge, which are qualities that are not necessarily obvious from paper qualifications.[218] After *KSR*, what the

206 Rogers, *supra* note 26, at 62.

207 *Id.*

208 Burk & Lemley, *Technology-Specific*, *supra* note 38, at 1188.

209 *Id.*

210 *Id.*

211 *See* Andrew B. Dzeguze, *The Devil in the Details: A Critique of* KSR*'s Unwarranted Reinterpretation of "Person Having Ordinary Skill*,*"* 10 COLUM. SCI. & TECH. L. REV. 1, 59 (2009).

212 *Id.* at 31.

213 501 F.3d 1254, 1256 (Fed. Cir. 2007).

214 *Id.*

215 *See* Rogers, *supra* note 26, at 96.

216 *See* Rantanen, *supra* note 70, at 762.

217 Rogers, *supra* note 26, at 95.

218 *Id.*

Federal Circuit has been doing, at least in the field of biochem, points towards continued deprecation of the importance of the PHOSITA.[219] It has done this by perpetrating standards from its own jurisprudence before *KSR*, often in direct conflict with *KSR*.[220] For instance, in *Pfizer*, the Federal Circuit required the court to consider whether the asserted prior art was a "lead compound."[221] A lead compound is a compound that "would be 'most promising to modify in order to improve upon its activity,'" representing a starting point leading to the invention.[222] This limited the scope of evidence to consider, and therefore the PHOSITA's freedom in choosing prior art.[223] The PHOSITA is forced to consider a lead compound and not allowed to consider familiar methods that they knew had the potential to solve the problem.[224] However, if the Federal Circuit truly wants to create stable, binding precedent, it must make a substantive attempt to comply with the Supreme Court's *KSR* instructions.[225] Specifically, it has to bring the PHOSITA to the forefront of fact gathering[226] in order to bring itself more into line with the statutory principles of patent law.[227]

D. The Supreme Court Has Signaled Its Intent to Limit the Issuance of Patents Through the Nonobviousness Standard of KSR

Patents are granted partially as a reward for discovering something new and useful, and partially to encourage continual innovation that benefits society.[228] The obviousness standard is the gatekeeper for inventions to enter the world of patentability, and the courts function as gatekeepers to allow only patentable inventions to pass through.[229] If the courts cannot perform this function adequately, they risk

[219] *Id.* at 98.

[220] *Id.* at 99.

[221] Pfizer Inc. v. Teva Pharm. USA, Inc., 555 F. App'x 961, 969 (Fed. Cir. 2014).

[222] *Id.* (quoting Takeda Chem. Indus. Ltd. V. Alphapharm Pty., Ltd., 492 F.3d 1350, 1357 (Fed. Cir. 2007).

[223] Rogers, *supra* note 26, at 98.

[224] *Id.*

[225] *See* Reilly, *supra* note 25, at 514.

[226] *See* Rogers, *supra* note 26, at 66.

[227] *See* 35 U.S.C. § 103 (2018); Dzeguze, *supra* note 211, at 26 (stating that the passage of § 103 "enshrined in statute the use of 'a person having ordinary skill in the art' as the proper frame of reference for analyzing obviousness").

[228] Burk & Lemley, *Policy Levers*, *supra* note 176, at 1576-77.

[229] *See* Cotropia, *supra* note 17, at 916; Petherbridge, *supra* note 17, at 907-08.

distorting the number of patents granted in biochem technologies without adequately balancing the following policy concerns.[230]

First, any over-proliferation of patents has to be balanced with the potential benefits of bringing new biochem innovations into the market.[231] Doing so would equalize private and social interests.[232] This is because granting patents encourages commercialization and efficient use of technological innovations that are potentially beneficial but have not realized their full potential.[233] For example, there is a private incentive to further develop a patented drug by submitting it for U.S. Food and Drug Administration ("FDA") approval, conducting clinical trials, and increasing its efficacy.[234] This in turn brings about future social benefits by giving patients access to a drug that has gone through the rigors of testing and improvement.[235]

Second, there are concerns that the public will be excluded from access to beneficial inventions.[236] This might arise, for example, when a court subsequently finds a patented invention to be obvious because it is simply a minor improvement over its predecessor.[237] Suppose there is a market demand for a pharmaceutical product that is being improved continually over time,[238] for instance enantiomers that are more bioavailable.[239] Inventors might be discouraged from performing

230 *See* Rantanen, *supra* note 70, at 716-17.

231 *See* Burk & Lemley, *Policy Levers*, *supra* note 176, at 1600-01.

232 *Id.*

233 *Id.*

234 *See* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 155-56 (2003); Henry G. Grabowski et al., *The Roles Of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFF. 302, 304-05 (2015); Renu Lal, *Patents and Exclusivity*, FDA/CDER SBIA CHRONICLES (May 19, 2015), https://www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm447307.pdf.

235 *See* Sean R. Tunis et al., *Practical Clinical Trials: Increasing the Value of Clinical Research for Decision Making in Clinical and Health Policy*, 290 J. AM. MED. ASS'N 1624, 1629 (2003); Judith M. Kramer, *Progress In The Last Half-Century: Breakthroughs In The Prevention And Treatment Of Disease*, APRIL 2010 CLINICAL TRIALS 1, 1 (2010).

236 Rantanen, *supra* note 70, at 716-17.

237 *See* Burk & Lemley, *Policy Levers*, *supra* note 176, at 1617-18.

238 *See id.* at 1616-18.

239 *See generally* Robert Hermann et al., *Enantiomer-Selective Pharmacokinetics, Oral Bioavailability, and Sex Effects of Various Alpha-Lipoic Acid Dosage Forms*, 6 CLIN. PHARMACOLOGY: ADVANCES & APPLICATIONS 195, 201-04 (2014) (demonstrating the approximately twofold higher bioavailability of *R*-alpha-lipoic acid over *S*-alpha-lipoic acid). Enantiomers are compounds that have the same chemical composition but are mirror-images of each other; this can cause them to have different physiological effects. *See id.* at 198-200; *Enantiomer*, *in* IUPAC COMPENDIUM OF CHEMICAL TERMINOLOGY 499 (2d ed. 1997), http:// http://goldbook.iupac.org/pdf/goldbook.pdf. Bioavailability refers

the research required to make the marginal change to an existing product, just because they think that it will be found obvious and therefore unpatentable.[240] Alternatively, the time and cost anticipated for making such a change might discourage inventors from modifying a drug that could potentially be found obvious.[241] This is especially so given the rigorous process of testing, clinical trials, and regulatory hurdles that every new drug must go through before FDA approval.[242]

Third, one can envision a potential increased burden on courts. Increased litigation could result from obviousness determinations that are not airtight to begin with, either at the PTO level or (in infringement cases) at the district court level.[243]

The Supreme Court in *KSR* briefly expressed concern with the proliferation of patents in general.[244] In doing so, it framed patents in terms of their value or utility.[245] The Court stated that a patentable invention has to be new and beneficial so that it does not "retard progress."[246] The overarching implication is that with the *KSR* decision the Supreme Court was signaling an intent to limit the number of patents granted, thereby asking the courts to be stricter gatekeepers.[247] As one scholar pronounced: "It is now plain that, for the Supreme Court, a wrongful patent grant is more harmful than a wrongful

to the percentage of an administered drug that actually reaches the bloodstream unaltered, as opposed to the percentage that is excreted out of the body without reaching its target organ. *See* Hermann et al., *supra* note 239, at 198-200.

240 *Cf.* Burk & Lemley, *Policy Levers*, *supra* note 176, at 1628 (discussing how any new microprocessor invented likely infringes on multiple existing patents).

241 *See id.* at 1624-25.

242 *See id.*

243 *See generally* Betsy Johnson, Comment, *Plugging the Holes in the Ex Parte Reexamination Statute*, 55 CATH. U. L. REV. 305 (2005).

244 *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 419 (2007) (stating that "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress").

245 *See id.*

246 *Id.*; *see also* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998) ("A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development.").

247 *See* Joseph Scott Miller, *Remixing Obviousness*, 16 TEX. INTELL. PROP. L.J. 237, 239 (2008). Furthermore, the empirical study conducted by Rantanen demonstrates that after *KSR*, the rate at which the Federal Circuit found inventions to be obvious has increased in all technological areas, and that the common perception now among patent attorneys is that it is easier to establish obviousness. Rantanen, *supra* note 70, at 739, 750-51.

denial."[248] Indeed, as stated in Part II.A, the Federal Circuit has found a significantly larger proportion of patent claims to be obvious post-*KSR* as compared to pre-*KSR*.[249] It is clear that *KSR* has shifted the landscape for federal courts and patent litigants towards a stricter standard for nonobviousness.[250]

III. THE FEDERAL CIRCUIT SHOULD UTILIZE PHOSITAS TO THEIR FULLEST EXTENT TO ESTABLISH STABLE PRECEDENT CONFORMING WITH KSR

A. Litigants Should Place a High Emphasis on Setting a Suitable PHOSITA Standard

At the trial level, fact-finding takes place during discovery, before the actual jury trial proceedings.[251] After discovery, upon reviewing all the litigants' evidence, the judge may decide to proceed to trial or grant a motion for summary judgment.[252] There are serious cost implications to gathering sufficient relevant evidence during discovery because such evidence could aid or defeat summary judgment.[253] As established in Part II.C, the PHOSITA plays a central role in determining nonobviousness.[254] The PHOSITA defines the scope of prior art and provides the level of skill to determine if a combination is obvious to try.[255] In other words, the selection of a suitable PHOSITA may be determinative of the outcome even before trial.[256] And if the case went to trial, the PHOSITA would still be the determinative factor in steering the jury to a resolution.[257] Because the PHOSITA is the outcome-determinative factor, each party should expend sufficient time and resources to identify a PHOSITA to best provide evidence in their favor.[258] This has the additional advantage of establishing good

[248] Miller, *supra* note 247, at 239.

[249] Rantanen, *supra* note 70, at 752-57.

[250] *See id.* at 739.

[251] FED. R. CIV. P. 26.

[252] *See* FED. R. CIV. P. 56; Steven S. Gensler & Lee H. Rosenthal, *Managing Summary Judgment*, 43 LOY. U. CHI. L.J. 517, 524-25 (2012); Rogers, *supra* note 26, at 55.

[253] Gensler & Rosenthal, *supra* note 252, at 527-28.

[254] Rogers, *supra* note 26, at 62-65.

[255] *Id.*

[256] *See id.* at 55.

[257] *See* Reilly, *supra* note 25, at 506-07.

[258] *See id.* at 504.

jurisprudence and precedence because the PHOSITA "will optimize fidelity to the technical merits" of any patent dispute.[259]

B. Courts Should View PHOSITAs as Valuable Allies

As examined in Part II.C, a secondary role of the PHOSITA is to allow the judge to focus on decision-making.[260] In order to properly adjudicate the dispute, the judge does not have to become an expert in the patent's subject matter because of the PHOSITA's presence.[261] As scholars note, judges are at "a serious disadvantage in trying to put themselves in the shoes" of a PHOSITA.[262] However, the reality is that some federal district judges still "loathe" patent cases because of the notoriously difficult subject matter.[263] As a result, one issue that arises is that judges might view the PHOSITA as an enigma and doubt the objectivity of the PHOSITA standard.[264]

Another issue with applying the PHOSITA standard lies with the jury.[265] The concern here is that lay jurors are also unable to accurately judge what a PHOSITA's opinions or expertise should be if these are beyond their own knowledge and understanding.[266] A PHOSITA as an expert witness might also offer their own opinion on whether a combination was obvious to try, which amounts to a factual conclusion.[267] As the subject matter becomes more technical and esoteric, the jury will have an even more incomplete understanding of the basis for the PHOSITA–expert witness's conclusion.[268] As a result, there is concern that the jury will eventually be left to rely on secondary criteria such as the demeanor, credentials, and superficial

[259] *Id.* at 505.

[260] *See* Burk & Lemley, *Technology-Specific*, *supra* note 38, at 1188.

[261] *Id.*

[262] *Id.* at 1196.

[263] Reilly, *supra* note 25, at 502-03; *e.g.*, Kathleen M. O'Malley et al., *A Panel Discussion: Claim Construction from the Perspective of the District Judge*, 54 CASE W. RES. L. REV. 671, 682 (2004) ("I have heard trial judges claim that they dislike patent litigation, partly because it is hard."). The O'Malley article further notes: "A lot of my colleagues hate patent cases. *Hate* them. They say, 'I tell you what, if you do my patent case, I'll do five ERISA cases.'" *Id.* at 683 n.31.

[264] *See* Reilly, *supra* note 25, at 503-04.

[265] *Id.* at 520.

[266] *Id.*

[267] *See* Rogers, *supra* note 26, at 63.

[268] Reilly, *supra* note 25, at 520.

plausibility of the PHOSITA–expert witness (hereinafter simply "PHOSITA").[269]

These issues concerning the judge and jury should push parties to spend sufficient time and effort to select PHOSITAs that will best represent their interests. Such PHOSITAs should be credible on paper, experienced in the pertinent subject matter, and be able to convey technical information in a way that a lay audience can understand.[270] To this end, my suggestion as the optimal choice in patent cases would be university educators. This group includes but is not limited to professors, lecturers, and graduate students — those with experience teaching in a lecture setting. There are several reasons for this. First, a university educator is most likely to possess the requisite technical, specialized knowledge that qualifies them as having ordinary skill in the art.[271] Second, having experience making specialized subject matter understandable to university students allows a PHOSITA to effectively convey the relevant information to the judge and jury.[272] Third, a university educator is likely to possess the intellectual credibility to effectively convince the jury, which is highly important to the litigants.[273]

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[269] *Id.* To clarify, by "PHOSITA–expert witness" I do not mean to suggest that all expert witnesses should be at the exact level of a PHOSITA. As discussed in Part I.A, the PHOSITA represents an objective legal standard. Burk & Lemley, *Technology-Specific*, supra note 38, at 1187-88. I am also not suggesting that the PHOSITA standard should be raised beyond the "ordinarily skilled" level. Jonathan J. Darrow, *The Neglected Dimension of Patent Law's PHOSITA Standard*, 23 HARV. J.L. & TECH. 227, 243-48 (2009). Here I mean to refer to an expert witness as one who satisfies at least the PHOSITA standard, and could very well be far above the level of a PHOSITA but is nevertheless still competent to inform a court what an "ordinarily skilled" artisan's opinion would be.

[270] *See id.* at 520-21.

[271] *See* Glenn D. Prestwich, *From Classroom to Courtroom: Can Academics Be Effective Expert Witnesses?*, 15 MATERIALS TODAY 406, 407 (2012); Reilly, *supra* note 25, at 515-16; Hung-San Kuo, Who Is the PHOSITA[?] 17 (Jan. 2015) (unpublished manuscript), available at https://www.researchgate.net/publication/316586503_Who_is_the_PHOSITA.

[272] *See, e.g.*, Prestwich, *supra* note 271, at 409 (noting that professors are "accustomed to seeing both sides of an argument, . . . exploring alternatives, [and] developing multiple explanations"); Jennifer A. Kingson, *The Professors Who Make a Case*, N.Y. TIMES (Nov. 6, 1988), http://www.nytimes.com/1988/11/06/education/the-professors-who-make-a-case.html ("Because I'm a teacher, part of the fun is to explain the whole thing in lay terms so that you can see the light bulbs come on with the jury.").

[273] Kingson, *supra* note 272 ("[P]rofessors are . . . perceived as intellectually honest, a quality most convincing to juries.").

Thus, both judge and jury should become accustomed to viewing a PHOSITA as someone who is actively aiding them in ultimately reaching a legal decision. For judges, this might involve ceding control and accepting a higher degree of reliance on the PHOSITA in understanding the facts.[274] For the jury, this involves a mutual exchange with the PHOSITA. The PHOSITA has to be a competent educator and convey the relevant facts in an understandable manner.[275] On the other side, the jury has to view the PHOSITA not as an interested party but as an instructor helping them to understand the subject matter.[276] To this end, the court could explicitly convey the PHOSITA's role via jury briefings, in addition to having PHOSITAs introduce themselves as such during trial.

A greater degree of reliance on PHOSITAs will thus bring the court closer to the "ideal outcome of the patent system" — an accurate judgment on technical merits.[277] As a legal outcome, this would be superior to the alternative method of structuring the relationship, in which the role of the PHOSITA is diminished or deprecated.[278] Using this method — erring on the side of the lay jury's comprehension — allows only a limited set of facts to be presented, with a suboptimal legal outcome.[279]

C. The Inventor Can Tailor the PHOSITA for the Case

As suggested above, litigants should choose their PHOSITAs from a nonexclusive pool of university educators.[280] One final concern might be that the process of selecting a PHOSITA is not entirely intuitive.[281] This is because selecting a suitable PHOSITA specializing in the field of interest can be a complex undertaking involving multiple considerations.[282] The inventor's patent attorney might view it as akin to looking for a needle in a haystack. However, in certain fields,

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[274] *See* Bryna Bogoch, *Discourse Dilemmas and Courtroom Control: The Talk of Trial Judges*, 25 LAW & SOC. INQUIRY 227, 241 (2000); Reilly, *supra* note 25, at 503-04.

[275] *See* Kingson, *supra* note 272.

[276] *See* Burk & Lemley, *Technology-Specific*, *supra* note 38, at 1187-88.

[277] Reilly, *supra* note 25, at 505.

[278] *See id.* at 529.

[279] *See id.* at 533-36.

[280] *Supra* Part III.B.

[281] *See* Rogers, *supra* note 26, at 97-98.

[282] *See* Reilly, *supra* note 25, at 515-17; Rogers, *supra* note 26, at 97-98; Michelle M. Umberger & Christopher G. Hanewicz, *Selecting Experts in Patent Cases* 2-3, PERKINS COIE (Aug. 2013), https://m.acc.com/chapters/wisc/upload/Selecting-Experts-in-Patent-Cases-Perkins-Coie-article-1.pdf.

especially science and engineering, there already exists a network in which researchers are aware of their colleagues in their field working at other institutions.[283] This is due to the social phenomenon known as "nested embeddedness."[284] Individual researchers are linked to their exogenous environment by being embedded in a scientific discipline which "consists of networks of scientists both within and outside their university."[285] Thus, if the inventor knows of a university researcher in the field with similar expertise, that researcher would likely qualify as a PHOSITA.[286] Otherwise, that putative candidate would probably know of a colleague at another university who would similarly be suited to fill the PHOSITA role.[287] This is likely to require far less effort and expense than, for example, combing for existing patents during due diligence.[288] Patent attorneys thus have a readily available database of PHOSITAs experienced in their field to choose from.

Additionally, a PHOSITA chosen this way will have a self-checking mechanism by which to evaluate their own suitability. Because the educator is experienced in their own field of knowledge, they will be aware of their own limitations. They will likely be cognizant of their own capacity to interpret and present the prior art to the court in an

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[283] This is especially true for researchers in academic fields that naturally lend themselves to the creation of patentable inventions. *See* Margherita Balconi et al., *Networks of Inventors and the Role of Academia: An Exploration of Italian Patent Data*, 33 RES. POL'Y 127, 144 (2004); Stefano Breschi & Christian Catalini, *Tracing the Links Between Science and Technology: An Exploratory Analysis of Scientists' and Inventors' Networks*, 39 RES. POL'Y 14, 16, 21 (2010) (also noting "the existence of a relatively high degree of connectedness between . . . two communities of researchers: scientific authors and industrial inventors"); Enrico Forti et al., *Bridges or Isolates? Investigating the Social Networks of Academic Inventors*, 42 RES. POL'Y 1378, 1386 (2013); *see also* Richard Van Noorden, *Scientists and the Social Network*, 512 NATURE 126, 128-29 (2014) (surveying the extent to which researchers utilize various internet social platforms to discover peers, search for and share relevant research literature, and comment on and discuss research results).

[284] Martin Kenney & W. Richard Goe, *The Role of Social Embeddedness in Professorial Entrepreneurship: A Comparison of Electrical Engineering and Computer Science at UC Berkeley and Stanford*, 33 RES. POL'Y 691, 692 (2004).

[285] *Id.*

[286] *See* Prestwich, *supra* note 271, at 407.

[287] *See generally* Balconi et al., *supra* note 283 (finding that academic inventors are more central and better connected than non-academic ones); Breschi & Catalini, *supra* note 283 (stating that there exists a high degree of connectedness, both within the academic research community and externally to the industry-inventor community); Forti et al., *supra* note 283 (finding that academic inventors tend to expand their networks, both within and without their original fields).

[288] *See* Sadhana Chitale et al., *Closing the Deal: A Checklist for Negotiating Robust Licensing Agreements*, 34 NATURE BIOTECHNOLOGY 1222, 1223 (2016).

effective manner.[289] A PHOSITA who cannot perform this function for a particular subject matter has the ability to suggest another more suitable colleague as a replacement.[290] This efficient self-selecting process allows the inventor and counsel to recruit the most ideal PHOSITA to aid in gathering supporting evidence for the litigation. This process again moves the judicial system and all parties closer to the ideal legal outcome.[291]

CONCLUSION

With *KSR*, the Supreme Court recommended that federal courts bring the PHOSITA to the forefront of the nonobviousness determination.[292] Nonobviousness is a legal conclusion relying heavily on a PHOSITA's accurate fact-finding.[293] Because the Federal Circuit is most often the final say in this legal conclusion, following the Supreme Court's *KSR* guidance would best serve the Federal Circuit.[294] The Federal Circuit must accord the PHOSITA a greater importance, and in doing so, exhort district courts to be diligent in ensuring optimal fact-finding.[295] Therefore, the Federal Circuit should always insist that all cases on appeal contain an adequate repository of relevant facts, or risk being summarily remanded for further discovery.

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[289] *Cf.* Deborah Sole and Amy Edmondson, *Situated Knowledge and Learning in Dispersed Teams*, 13 BRIT. J. MGMT. S17, S19-S20, S24-S25 (2002) (observing that when a team of polymer scientists encountered unexpected results in their experiments, they reasoned that "the source of problems could be one or more unfamiliar ingredients in the recipe," thus recognizing a need to "consult[] specialist colleagues . . . who had done prior work exploring the chemistry of [the] chemicals").

[290] *See generally* Balconi et al., *supra* note 283; Breschi & Catalini, *supra* note 283; Forti et al., *supra* note 283. Anecdotally, when I was a summer associate working on a patent litigation case, the original expert witness we interviewed (a chemistry professor) was unsuitable, but ended up recommending another chemistry professor who turned out to be suitable.

[291] Reilly, *supra* note 25, at 505.

[292] Rogers, *supra* note 26, at 65.

[293] *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007); Pfizer Inc. v. Teva Pharm. USA, Inc., 555 F. App'x 961, 968 (Fed. Cir. 2014); *In re* Kubin, 561 F.3d 1351, 1355 (Fed. Cir. 2009).

[294] *See* Rantanen, *supra* note 70, at 721-22.

[295] *See id.* at 742-45.